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PTO/SB/21 (03-03)

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(to be used for all correspondence after initial filing)

Application Number	10/679,081
Filing Date	10/03/2003
First Named Inventor	Hans-Michael Dosch
Art Unit	1632
Examiner Name	
Attorney Docket Number	2560.001

Total Number of Pages in This Submission

7

ENCLOSURES (Check all that apply)

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Firm or Individual	Ferris H. Lander McHale & Slavin, P.A.
Signature	<i>Ferris H. Lander</i>
Date	6/11/2004

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IN RE APPLICANT : Hans-Michael Dosch et al

INVENTION : PREVENTION OF PRIMARY SJOGREN'S
SYNDROME BY ICA69 DEFICIENCY

SERIAL NUMBER : 10/679,081

FILING DATE : October 3, 2003

EXAMINER : (unassigned)

GROUP ART UNIT : 1632

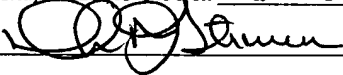
ATTORNEY DOCKET NO. : 2560.001

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Pursuant to the Duty to Disclose under 37 CFR §1.56, the references cited on the accompanying form PTO/SB/08A and PTO/SB/08B are hereby brought to the attention of the Examiner for independent evaluation. A copy of each reference is enclosed. The first (7) references were cited in an International Search Report issued in corresponding International Patent Application No. PCT/CA03/01535.

Applicants submit that the present invention is patentable over these references.

Date 6/10/2004

Respectfully submitted,

By Ferris H. Lander
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PTO/SB/08A (08-03)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/679,081
Filing Date	10/3/2003
First Named Inventor	Hans-Michael Dosch
Art Unit	1632
Examiner Name	
Attorney Docket Number	2560.001

Sheet 2 of 5

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		S. WINER et al, "ICA69null nonobese diabetic mice develop diabetes, but resist disease acceleration by cyclophosphamide", Journal of Immunology, 168(1):475-482 (January, 2002)	
		S. MARTIN et al, "Autoantibodies to the islet antigen ICA69 occur in IDDM and in rheumatoid arthritis", Diabetologia, 38(3):351-355 (March, 1995)	
		S. WINER et al, "ICA69null NOD congenic mice are protected from sialitis and cyclophosphamide-accelerated diabetes", Diabetes, 50(Supp 2):A503 (June, 2001) Abstract XP008028882, 2114-PO	
		K. YANAGI et al, "Anti-120-kDa alpha-fodrin immune response with Th1-cytokine profile in the NDO mouse model of Sjogren's syndrome", Eur. J. Immunol., 28(10):3336-3345 (October, 1998)	
		S. WINER et al, "Primary Sjogren's syndrome and deficiency of ICA69", The Lancet, 360(9339):1063-1069 (October, 2002)	
		R. FOX et al, "Update in Sjogren syndrome", Current Opinion in Rheumatology, 12:391-398 (2000)	
		J. JAMES et al, "Role of viruses in systemic lupus erythematosus and Sjogren syndrome", Current Opinion in Rheumatology, 13:370-376 (2001)	
		R. FOX et al, "Current issues in the diagnosis and treatment of Sjogren's syndrome", Current Opinion in Rheumatology, 11(5):364-371 (September, 1999)	
		J. HARLEY et al, "Anti-Ro (SS-A) and anti-La (SS-B) in patients with Sjogren's syndrome", Arthritis and Rheumatism, 29(2):196-206 (February, 1986)	
		O. BILLAUT-MULOT et al, "SS-56, a novel cellular target of autoantibody responses in Sjogren syndrome and systemic lupus erythematosus", The Journal of Clinical Investigation, 108(6):861-869 (September, 2001)	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Application Number	10/679,081		
		Filing Date	10/3/2003		
		First Named Inventor	Hans-Michael Dosch		
		Art Unit	1632		
		Examiner Name			
Sheet	3	of	5	Attorney Docket Number	2560.001

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		N. HANEJI et al, "Identification of alpha-Fodrin as a candidate autoantigen in primary Sjogren's syndrome", Science, 276:604-607 (April, 1997)	
		M. KUWANA et al, "Autoantibodies to the amino-terminal fragment of beta-Fodrin expressed in glandular epithelial cells in patients with Sjogren's syndrome", The Journal of Immunology, 167:5449-5456 (2001)	
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		R. HOFFMAN et al, "Sjogren's syndrome in MRL/l and MRL/n mice", Arthritis and Rheumatism, 27(2):157-165 (February, 1984)	
		N. HANEJI et al, "A new animal model for primary Sjogren's syndrome in NFS/sld mutant mice", The Journal of Immunology, 153:2769-2777 (1994)	
		J. BRAYER et al, "Sjogren's syndrome: immunological response underlying the disease", Arch. Immunol. Ther. Exp., 49:353-360 (2001)	
		C. ROBINSON et al, "A novel NOD-derived murine model of primary Sjogren's syndrome", Arthritis & Rheumatism, 41(1):150-156 (January, 1998)	
		W. KARGES et al, "Loss of self-tolerance to ICA69 in nonobese diabetic mice", Diabetes, 46:1548-1556 (October, 1997)	
		H.-MICHAEL DOSCH et al, "Persistent T cell anergy in human type 1 diabetes", The Journal of Immunology, 163:6933-6940 (1999)	

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				Art Unit	1632
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Sheet	4	of	5	Attorney Docket Number	2560.001

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		M. PILON et al, "The diabetes autoantigen ICA69 and its Caenorhabditis elegans homologue, ric-19, are conserved regulators of neuroendocrine secretion", Molecular Biology of the Cell, 11:3277-3288 (October, 2000)	
		S. WINER et al, "ICA69 null nonobese diabetic mice develop diabetes, but resist disease acceleration by cyclophosphamide", The Journal of Immunology, 168:475-482 (2002)	
		W. KARGES et al, "Gene expression of islet cell antigen p69 in human, mouse, and rat", Diabetes, 45:513-521 (April, 1996)	
		S. WINER et al, "Type 1 diabetes and multiple sclerosis patients target islet plus central nervous system autoantigens; nonimmunized nonobese diabetic mice can develop autoimmune encephalitis", The Journal of Immunology, 166:2831-2841 (2001)	
		D. SERREZE et al, "B lymphocytes are essential for the initiation of T cell-mediated autoimmune diabetes: analysis of a new 'speed congenic' stock of NOD.lgmu null mice", J. Exp. Med., 184:2049-2053 (November, 1996)	
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		R. HUNGER et al, "Male gonadal environment paradoxically promotes dacryoadenitis in nonobese diabetic mice", J. Clin. Invest., 101(6):1300-1309 (March, 1998)	
		W. CHEN et al, "Evidence that a peptide spanning the B-C junction of proinsulin is an early autoantigen epitope in the pathogenesis of type 1 diabetes", The Journal of Immunology, 167:4926-4935 (2001)	
		C. LAFITTE et al, "Neurological complications of primary Sjogren's syndrome", Journal of Neurology, 248(7):577-584 (July, 2001)	

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Sheet	5	of	5	Attorney Docket Number	2560.001

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		A. ANDONOPOULOS et al, "The spectrum of neurological involvement in Sjogren's syndrome", The British Journal of Rheumatology, 29:21-23 (1990)	
		K. MALINOW et al, "Subacute sensory neuronopathy secondary to dorsal root ganglionitis in primary Sjogren's syndrome", Ann. Neurol., 20:535-537 (1986)	
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		R. MASAGO et al, "Elevated Proapoptotic Bax and Caspase 3 activation in the NOD.scid model of Sjogren's syndrome", Arthritis & Rheumatism, 44(3):693-702 (March, 2001)	
		C. ROBINSON et al, "Genetically programmed development of salivary gland abnormalities in the NOD (nonobese diabetic)-scid mouse in the absence of detectable lymphocytic infiltration: a potential trigger for sialoadentitis of NOD mice", Clin. Immunol. Immunopathol., 79(1):50-59 (April, 1996)	
		J. GROOM et al, "Association of BAFF/BLyS overexpression and altered B cell differentiation with Sjogren's syndrome", The Journal of Clinical Investigation, 109(1):59-68 (January, 2002)	

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